AUSTRALIAN DAIRY CORPORATION

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)

Comments on Section 305 - 'Registration'

The Australian Dairy Corporation (ADC) welcomes the opportunity to provide comments on the United States of America Government's proposed framework for registration of domestic and foreign food manufacturing facilities, as published in the Notice of proposed rulemaking on Registration of Food Facilities Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*.

Australia as a long-term exporter of dairy products to the United States has a direct interest in the US requirements for the importation of these products. The Australian Dairy Industry (ADI) is committed to a food safety system that delivers high quality dairy products to Australia's trading partners.

The US is a highly competitive food market and any additional costs imposed on imported dairy products could have two commercially adverse impacts; on the competitiveness of the imported dairy product(s) and the consumer price.

Mandatory information

The mandatory requirement that organisations exporting to the US conduct their commercial business through a specified (and mandatory) US agent will present a new and burdensome business practice upon organisations (as well as additional costs), particularly for smaller operators.

The ADC questions whether the FDA requirement for organisations applying for registration to have a mandatory US agent acting on their behalf for the one-off registration process is necessary for the protection of human or animal health and does not constitute a disguised restriction on trade (as per Article 2.3 of the SPS Agreement). In essence the registration requirement duplicates existing arrangements at extra cost, and provides no additional "security benefit" to the US.

It is administratively cumbersome where exporters have several agents. Australian industry has concerns with regard to this aspect. The most likely agent to be used by an Australian exporter would be an importer/customs broker. However, many Australian exporters use more than one agent to handle their consignments depending upon the port

of entry into the US. Their concerns relate to issues of confidentiality and commercial sensitivity when the chosen agent is dealing with business information pertaining to another US-based agent not covered by the registration.

The ADC recommends that the US agent requirement for registration purposes be changed to an optional information field to accommodate varied business practices used by organisations, thus not introducing trade restrictive obligations.

Controls applying to establishments producing goods for export to the United States include regular audits by US authorities (FDA and FSIS). Australia believes that under the *Export Control Act 1982* existing Australian Quarantine and Inspection Service (AQIS) export registration requirements for facilities will provide sufficient control to meet FDA needs to achieve the outcomes of the Bioterrorism Act. AQIS can also supply the FDA with a list of AQIS export registered establishments on a regular basis.

In considering equivalence (as per Article 4 of the SPS Agreement) in the assessment and registration of export food manufacturing facilities, there is a strong rationale to utilise the Australian export registration requirements. The proposed rule allows for an exemption from registration for facilities that are under the control of another agency within the USDA. Currently, meat, poultry and egg products are controlled by the USDA's Food Safety and Inspection Service (FSIS). Foreign premises dealing with these products are exempt from the Bioterrorism Act's registration requirements. The FSIS accepts AQIS registration of export facilities exporting FSIS controlled products to the USA. Thus, the ADC believes that to maintain consistency the FDA should also accept AQIS method of export registration. The ADC therefore believes that the provisions of Section 305 of the Bioterrorism Act could be met through an equivalence-based approach.

The information requirements of AQIS's export registration procedures exceed those of the proposed rule by requiring the applicant to provide business name, number and address; alternative trading names; name, company position, date of birth and home addresses of all persons who manage or control the day to day operations for the establishment; the proposed operations and overseas markets the application seeks to serve; and the name and contact details (including home address) of the applicant. The applicant also provides a signed declaration stating the information provided is true in every detail. AQIS then assesses the acceptability of the application, including conducting 'fit and proper persons' reviews on all people listed in the application prior to granting export registration.

The FDA has only allowed two months for all facilities world-wide to register their premises. This will present an enormous task for FDA to process the applications considering the FDA estimates there may be as many as 200,000 domestic and 200,000 foreign facilities to register. This appears to be an unrealistic timeframe to achieve processing of all applications submitted for registration prior to 12 December 2003. The proposed FDA electronic registration process will give facilities an immediate registration number upon completion of the application, thus not allowing any

meaningful examination of the applicant or application such as that that is undertaken by AQIS.

Under the Bioterrorism Act, FDA is authorized to require that the registration include the food product categories set forth in 21 C.F.R. §170.3. FDA's stated rationale for this requirement is that it will assist the agency in communicating with facilities that may have products that are the subject of a food security or safety concern for example FDA could alert all facilities that handle cheese foods.

FDA concedes that the list of food categories in 21 C.F.R. §170.3 is outdated and incomplete. The regulation dates to the early 1970s and has not been amended since. Whole categories of commonly marketed foods are not listed, including, as FDA itself notes, dietary supplements where dairy products are an essential component.

Customs duplication

There is considerable duplication of the information required by US Customs and that required by FDA. It is apparent that no immediate measures are being put into place to address this issue and thereby facilitate the introduction of these proposals in a more efficient manner.

Further clarification

There are a number of points that the ADC seeks further clarification on, namely:

Can a corporate headquarters/central office/parent company register multiple facilities on the one registration form? The ability to register multiple facilities is preferable.

If a registration is not effected properly by an authorised agent where does the liability rest for rectifying the error and costs for storage of product etc under the regulations?

When must a registration be updated?

What happens if a facility is not registered?

May a registration be revoked?

Closing Comments

In conclusion the ADC urges the FDA to apply its risk mitigation measures under this Act in a manner that minimises regulatory impact on industry, has regard to existing food regulation and export certification systems in Australia as well as to the overall WTO rights and obligations of Australia and the USA.

Submitted by the Australian Dairy Corporation

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